



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0601; FRL-9111-01-OCSP]

Fluensulfone; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes and removes tolerances for residues of fluensulfone in or on multiple crops that are identified later in this document. The Interregional Research Project Number 4 (IR-4) requested these tolerance actions under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0601, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to

provide customer service via email, phone, and webform. For the latest status information on EPA/DC services, docket access, visit <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in

accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2020-0601 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0601, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/where-send-comments-epa-dockets>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of June 28, 2021 (86 FR 33922) (FRL-10025-08) EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E8861) by IR-4, Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.680 be amended by establishing tolerances for residues of the sum of fluensulfone, 5-chloro-2-[(3,4,4-trifluoro-3-buten-1-yl)sulfonyl]thiazole and its metabolite, 3,4,4-trifluoro-but-3-ene-1-sulfonic acid, calculated as the stoichiometric equivalent of fluensulfone, in or on the commodities: Beet, sugar, dried pulp at 0.3 parts per million (ppm); Beet, sugar, leaves at 4 ppm; Beet, sugar, molasses at 1.5 ppm; Beet, sugar, roots at 0.2 ppm; *Brassica*, leafy greens, subgroup 4-16B at 20 ppm; Celtuce at 4 ppm; Fennel, Florence, fresh leaves and stalk at 4 ppm; Kohlrabi at 1.5 ppm; Leafy greens subgroup 4-16A at 4 ppm; Leaf petiole vegetable subgroup 22B at 4 ppm; and Vegetable, *Brassica*, head and stem, group 5-16 at 1.5 ppm. The petition also requested to remove established tolerances for residues of the sum of fluensulfone, 5-chloro-2-[(3,4,4-trifluoro-3-buten-1-yl)sulfonyl]thiazole and its metabolite, 3,4,4-trifluoro-but-3-ene-1-sulfonic acid, calculated as the stoichiometric equivalent of fluensulfone, in or on the following commodities: *Brassica*, head and stem, subgroup 5A at 1.5 ppm; *Brassica*, leafy greens, subgroup 5B at 20 ppm; and Vegetables, leafy, except *Brassica*, group 4 at 4 ppm because these commodities would be covered by the new tolerances established for the crop group conversions above. That document referenced a summary of the petition prepared by IR-4, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA is establishing one tolerance at a different level than petitioned for. A discussion of this revision to the petitioned-for tolerance can be found in section IV.C. In addition, IR-4 initially petitioned

for tolerances for multiple sugar beet commodities but withdrew their request for these tolerances and the new use on sugar beet on April 8, 2021. EPA is therefore not establishing tolerances for the sugar beet commodities.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluensulfone including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluensulfone follows.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, and EPA considers referral back to those sections as

sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a number of tolerance rulemakings for fluensulfone, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to fluensulfone and established tolerances for residues of that chemical. EPA is incorporating previously published sections from those rulemakings that remain unchanged as described further in this rulemaking.

Toxicological profile. For a discussion of the Toxicological Profile of fluensulfone, see Unit III.A. of the fluensulfone tolerance rulemaking published in the *Federal Register* of April 13, 2018 (83 FR 15971) (FRL-9975-76).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for fluensulfone used for human risk assessment, see Unit III.B. of the fluensulfone tolerance rulemaking published in the *Federal Register* of June 1, 2016 (81 FR 34896) (FRL-9946-07).

Exposure assessment. This action converts existing crop group tolerances for *Brassica*, head and stem, subgroup 5A; *Brassica*, leafy greens, subgroup 5B; and Vegetables, leafy, except *Brassica*, group 4, which were established in the fluensulfone tolerance rulemaking published in the *Federal Register* of May 24, 2019 (84 FR 24042) (FRL-9992-69), to new tolerances for *Brassica*, leafy greens, subgroup 4-16B; Celtuce; Fennel, Florence, fresh leaves and stalk; Kohlrabi; Leaf petiole vegetable subgroup 22B; Leafy greens subgroup 4-16A; and Vegetable, *Brassica*, head and stem, group 5-16. Although tolerance levels for some commodities have changed as a result of these crop group conversions, they have not impacted the residue estimates or Estimated Drinking Water Concentrations (EDWCs) used in the dietary exposure assessment for the May 24, 2019 rulemaking for these commodities. Therefore, the dietary exposure assessment

remains the same. For a description of the rest of the EPA approach to and assumptions for the exposure assessment, including with respect to dietary exposure, residential exposure, and cumulative effects, see Unit III.C. of the May 24, 2019 rulemaking.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the May 24, 2019 rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD; they are 21% of the aPAD for infants (<1 year old), the group with the highest estimated exposure. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 4.8% of the cPAD for infants (<1 year old), the group with the highest estimated exposure. EPA concluded that the combined food, water, and residential exposures result in aggregate MOEs above the level of concern of 100 for all relevant exposure scenarios and are not of concern. As the chronic dietary endpoint and dose are protective of potential cancer effects, fluensulfone is not expected to pose a dietary or aggregate cancer risk of concern.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general

population, or to infants and children, from aggregate exposure to fluensulfone residues. More detailed information on this action can be found in the document entitled, “Fluensulfone. Petition for Crop Group Conversions to *Brassica* Head and Stem Vegetable Group 5-16, *Brassica* Leafy Greens Subgroup 4-16B, Leafy Greens Subgroup 4-16A, Leaf Petiole Vegetable Subgroup 22B, Kohlrabi, Celtuce, and Florence Fennel” by going to the docket established by this action, which is described under ADDRESSES.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the May 24, 2019 rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). EPA may establish a tolerance that is different from a Codex MRL; however, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The tolerance for crop subgroup 4-16B (20 ppm) is harmonized with the Codex MRLs for mizuna and mustard greens; all other Codex MRLs for crops within crop subgroup 4-16B are lower than 20 ppm. The tolerance for kohlrabi (1.5 ppm) is harmonized with the Codex MRL for kohlrabi. The tolerance for crop subgroup 4-16A (4 ppm) is harmonized with the Codex MRL for spinach; all other Codex MRLs for commodities within crop subgroup 4-16A are lower than 4 ppm. The tolerance for crop subgroup 22B (2 ppm) is harmonized with the Codex MRL for celery. The tolerance for crop group 5-16 (1.5 ppm) is harmonized with all Codex commodities within the crop

group except Chinese cabbage, napa, which has a Codex MRL of 1 ppm. There are no Codex MRLs for Florence fennel and celtuce.

C. Revisions to Petitioned-For Tolerances

The petitioner proposed a tolerance value of 4 ppm for leaf petiole vegetable subgroup 22B based on the existing tolerance for vegetables, leafy, except *Brassica*, crop group 4. Instead, EPA is establishing a tolerance value of 2 ppm for crop subgroup 22B to harmonize with the Codex MRL for celery. EPA analyzed the existing celery data, which supports a tolerance of 2 ppm according to the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedure.

D. International Trade Considerations

In this rule, EPA is establishing tolerances for fluensulfone residues in or on the leaf petiole vegetable subgroup 22B at 2 ppm, which is lower than the existing tolerance in or on vegetables, leafy, except *Brassica*, group 4, which includes cardoon; celery; celery, Chinese; and rhubarb (all at 4 ppm and all part of the leaf petiole vegetable subgroup 22B). The Agency believes this revised, lower tolerance is appropriate because it is harmonized with the Codex MRL for celery and is supported by available residue data.

In accordance with the World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (SPS) Agreement, EPA intends to notify the WTO of the changes to these tolerances in order to satisfy its obligations under the Agreement. In addition, the SPS Agreement requires that Members provide a "reasonable interval" between the publication of a regulation subject to the Agreement and its entry into force to allow time for producers in exporting Member countries to adapt to the new requirement. Accordingly, EPA is establishing an expiration date for the existing tolerance for residues of fluensulfone in or on vegetables, leafy, except *Brassica*, group 4 to allow it to remain in effect for a period of six months after the effective date of this

final rule. After the six-month period ends, this tolerance will expire, as indicated in the regulatory text, and allowable residues on cardoon; celery; celery, Chinese; and rhubarb must conform to the new tolerance for leaf petiole vegetable subgroup 22B. This reduction in the tolerance level is not discriminatory; the same food safety standard contained in the FFDCa applies equally to domestically produced and imported foods. The new tolerance level is supported by available residue data.

V. Conclusion

Therefore, tolerances are established for residues of fluensulfone in or on *Brassica*, leafy greens, subgroup 4-16B at 20 ppm; Celtuce at 4 ppm; Fennel, Florence, fresh leaves and stalk at 4 ppm; Kohlrabi at 1.5 ppm; Leaf petiole vegetable subgroup 22B at 2 ppm; Leafy greens subgroup 4-16A at 4 ppm; and Vegetable, *Brassica*, head and stem, group 5-16 at 1.5 ppm.

Additionally, the following existing tolerances are unnecessary due to the establishment of the above tolerances: *Brassica*, head and stem, subgroup 5A; *Brassica*, leafy greens, subgroup 5B; and Vegetables, leafy, except *Brassica*, group 4. Therefore, existing tolerances for residues of fluensulfone in or on *Brassica*, head and stem, subgroup 5A and *Brassica*, leafy greens, subgroup 5B are removed, and to satisfy international trade obligations, the existing tolerance for residues of fluensulfone in or on Vegetables, leafy, except *Brassica*, group 4 expires six months after the effective date of this final rule.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCa section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject

to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCFA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCFA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides, and pests, Reporting and recordkeeping requirements.

Dated: October 22, 2021.

Catherine Aubee,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.680, amend table 1 to § 180.680 following paragraph (a) by:

- a. Adding in alphanumerical order to the table entries for “*Brassica*, leafy greens, subgroup 4-16B”; “Celtuce”; “Fennel, Florence, fresh leaves and stalk”; “Kohlrabi”;

“Leaf petiole vegetable subgroup 22B”; “Leafy greens subgroup 4-16A”; and

“Vegetable, *Brassica*, head and stem, group 5-16”;

b. Removing the entries for “*Brassica*, head and stem, subgroup 5A”; and “*Brassica*, leafy greens, subgroup 5B”; and

c. Revising the entry for “Vegetables, leafy, except *Brassica*, group 4”.

The additions read as follows:

§ 180.680 Fluensulfone; tolerances for residues.

(a) * * *

Table 1 to § 180.680

Commodity	Parts per million
* * * * *	* *
<i>Brassica</i> , leafy greens, subgroup 4-16B	20
Celtuce	4
Fennel, Florence, fresh leaves and stalk	4
* * * * *	* *
Kohlrabi	1.5
Leaf petiole vegetable subgroup 22B	2
Leafy greens subgroup 4-16A	4
* * * * *	* *
Vegetable, <i>Brassica</i> , head and stem, group 5-16	1.5
* * * * *	* *
Vegetables, leafy, except <i>Brassica</i> , group 4 ¹	4
* * * * *	* *

¹ This tolerance expires on [INSERT DATE 6 MONTHS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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